REMARKS

Claims 2-18 were pending in the Application before entrance of the present Amendment. Claims 14-18 were withdrawn from consideration by the Examiner. Claim 1 was previously canceled. By the present Amendment, claims 10, 17, and 18 are canceled, and claims 2, 8, and 9 are currently amended. Support for the amendment to substituent R_2 in claim 2 can be found in the definition of R_4 in the pending claims. No new matter has been added to the Application by this Amendment. After entrance of the present Amendment, claims 2-9 and 11-16 are pending, and claims 2-9 and 11-13 are pending and under consideration by the Examiner.

Each of the rejections levied by the Examiner in the Office Action is addressed in turn below.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 2-7 and 10-13 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner asserts that the specification, while being enabling for some of the claimed compounds, does not reasonably provide enablement for the full scope of the claims. The Examiner alleges that "[t]he specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims." Applicant respectfully disagrees.

The specification enables one of ordinary skill in the art to make the claimed compounds.

Applicant submits that the amended claims are enabled. Upon review of the reaction schemes I-II (on pages 25-28), the eighteen representative synthetic examples (on pages 32-56), and the exemplary compounds (on pages 57-74) of the specification, one of ordinary skill in the art could make the claimed compounds without undue experimentation.

The specification enables the use of the claimed compounds.

Section 2164.01(c) of the MPEP entitled "*How to Use the Claimed Invention*" sets forth the requirements for enabling the use of a claimed invention:

> "If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are

> known and contemplated, 35 U.S.C. § 112 is satisfied. *In re Johnson*, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings*, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). See also *In re Brana,* 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993).
>
> "[W]hen a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for non-enablement based on how to use."

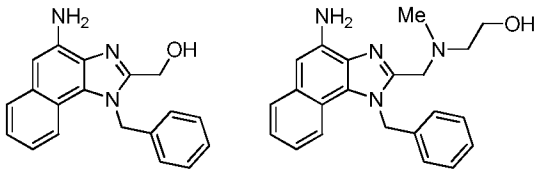
The Application, as originally filed, teaches one of ordinary skill in the art how to use the claimed compounds. The specification discloses that the invention "relates to the use of these compounds as immunomodulators, for inducing cytokine biosynthesis in animals and in the treatment of diseases inducing viral and neoplastic diseases" (page 1, lines 10-13, of the published international PCT application, WO 2005/066170). The Application also teaches experimental procedures for assaying for the induction of cytokine biosynthesis in human cells on pages 56-57. Therefore, the enablement requirement under § 112 is satisfied for the claimed compounds because Applicant has provided a use for the compounds. The Examiner has not provided any evidence that the claimed compounds could not be used for the stated purpose. Applicant therefore respectfully requests the removal of this rejection.

Rejections under 35 U.S.C. § 103

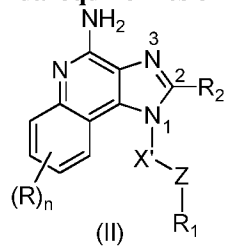
The Examiner has also rejected claims 2-13 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent 6,677,348 to Heppner *et al.* ("Heppner"), in view of U.S. Patent 6,664,264 to Dellaria *et al.* ("Dellaria '264"), U.S. Patent 6,670,372 to Dellaria *et al.* ("Dellaria '372"), European Patent Application EP 145,340 to Gerster *et al.* ("Gerster '340"), U.S. Patent 4,688,338 to Brown *et al.*, ("Brown"), the published international PCT application WO 1992/15582 to Gerster ("Gerster '582"), U.S. Patent 5,389,640 to Gerster *et al.* ("Gerster '640"), U.S. Patent 7,038,051 to Gerster *et al.* ("Gerster '051"), U.S. Patent 7,038,051 to Kato *et al.* ("Kato"), and Japanese Patent Publication No. 11-80156 to Mokuriku Seiyaku Co., Ltd ("Mokuriku"). Applicant notes that Brown teaches orthopedic inserts and believes that the citation of this reference is in error.

Gerster '340, Gerster '582, Gerster '640, and Kato disclose compounds which are structurally dissimilar from the claimed compounds. Gerster '340, Gerster '582, Gerster '640, and Kato disclose compounds (shown below) which have *N1*-substituted carbon linkers, but which lack the linker Z, wherein Z is an alkenylene or alkynylene linker, and wherein Z is bound to an aryl group. Therefore, Gerster '340, Gerster '582, Gerster '640, and Kato do not teach or suggest the presently claimed imidazoquinolines substituted with aryl groups at the *N*1 position via an alkenylene or alkynylene linker Z. Further, Gerster '340, Gerster '582, Gerster '640, and Kato do not provide any suggestion or motivation to modify their compounds by the addition of an alkenylene or alkynylene linker to arrive at the claimed compounds.

Representative compounds of Gerster '340, Gerster '582, Gerster '640, and Kato



Claimed imidazoquinolines of formula (II)



(II)

Z is alkenylene or alkynylene

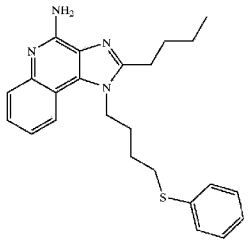
The Federal Circuit has ruled that structural similarity *and* some motivation in the prior art are both required to establish a *prima facie* case of obviousness in the chemical arts. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492. F.3d 1350 (Fed. Cir. 2007). Applicant respectfully contends that the Examiner's arguments do not satisfy these two requirements.

> We have held that "structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness." *Dillon*, 919 F.2d at 692. In addition to structural similarity between the compounds, a prima facie case of obviousness also requires a showing of

"adequate support in the prior art" for the change in structure. *In re Grabiak*, 769 F.2d 729, 731-32 (Fed. Cir. 1985).

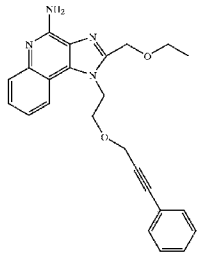
Dellaria '264 discloses compounds (such as that shown below) which have *N1*-substituted carbon linkers interrupted with -S-, -SO-, or $-SO_2-$, but which lack an alkenylene or alkynylene linker Z. Therefore, the compounds of Dellaria '264 do not cure the deficiency of Gerster '340, Gerster '582, Gerster '640, and Kato because Dellaria '264 does not teach or suggest an alkenylene or alkynylene linker Z. As such, the combination of Dellaria '264 with Gerster '340, Gerster '582, Gerster '640, and Kato does not teach or suggest to one of ordinary skill in the art the instantly claimed imidazoquinolines substituted with aryl groups at the *N*1 position via an alkenylene or alkynylene linker Z, and wherein linker Z is bound to an aryl group. Also, linker Z of the presently claimed compounds is not interrupted by a sulfur atom as are the linkers of Dellaria.

Example 1 of Dellaria '264

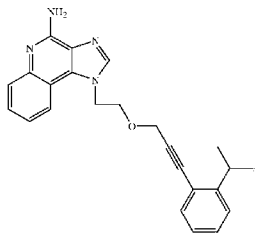


Heppner and Dellaria '372 disclose compounds (such as those shown below) which lack the linker Z, wherein Z is an alkenylene or alkynylene linker. Instead, the compounds of Heppner and Dellaria '372 recite linkers which can be **-O-**CH_2-CH=CH- or **-O-**CH_2-C≡C-. All of the compounds of Heppner and Dellaria '372 feature an oxygen linkage. Heppner and Dellaria '372 do not teach or suggest the removal of the oxygen linkage. Therefore, the compounds of Heppner and Dellaria '372 do not cure the deficiency of Gerster '340, Gerster '582, Gerster '640, and Kato because Heppner and Dellaria '372 do not teach or suggest an alkenylene or alkynylene linker Z, without the oxygen linkage. As such, the combination of Heppner and Dellaria '372 with Gerster '340, Gerster '582, Gerster '640, and Kato does not teach or suggest to one of ordinary skill in the art the instantly claimed imidazoquinolines substituted with aryl groups at the *N*1 position by an alkenylene or alkynylene linker Z, which is not interrupted by an oxygen atom.

Example 122 of Heppner



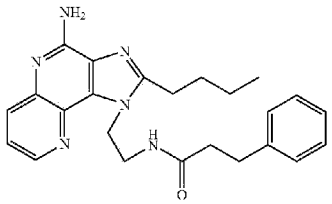
Example 7 of Dellaria '372



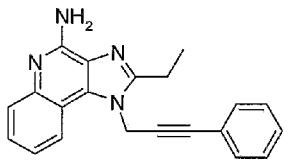
The Examiner alleges that the above-mentioned differences between the linker regions which correspond to linker Z become "equivalent" in view of "Gerster 7,038,051 [which] teaches the equivalency of different linkages at the same position as the Z." Applicant disagrees, and notes that the Examiner has not specifically indicated how Gerster '051 teaches the equivalency among linkers at *N*1.

However, in the interest of furthering prosecution Applicant addresses this assertion. Even if the linkers Z in the compounds of Gerster '051 are assumed to be equivalent, such an equivalency could not reasonably be applied to compounds which do not resemble those of Gerster '051. The compounds of the present Application and those of the cited art do not resemble the compounds of Gerster '051. Gerster '051 does not recite imidazoquinolines. Instead, the compounds of Gerster '051 are imidazonaphthyridines. Further, the imidazonaphthyridine core of Gerster '051 is substituted with amide- and sulfonamide-containing linkers at *N*1, whereas the presently claimed imidazoquinolines are substituted with unsaturated hydrocarbon linkers at *N*1 with no interrupting heteroatoms. Therefore, one of ordinary skill in the art would not understand Gerster to teach such a modification as the Examiner has mentioned with a reasonable expectation of success.

Example 85 of Gerster '051



Example 4 of the present Application



One of ordinary skill in the art would not reasonably apply the Gerster '051 linkers to the presently claimed compounds. As mentioned, structural similarity *and* some motivation in the prior art are both required to establish a *prima facie* case of obviousness in the chemical arts. The

imidazonaphthyridines of Gerster '051 are structurally dissimilar from the claimed imidazoquinolines and do not cure the deficiency of the imidazoquinolines of Gerster '340, Gerster '582, Gerster '640, and Kato. Therefore, Gerster '051 does not teach or suggest that the linkers Z of the claimed imidazoquinolines are equivalent to the corresponding linkers of the compounds of the cited art. Applicant respectfully requests the removal of the rejection under § 103.

Double Patenting Rejection

The Examiner provisionally rejected claims 2-13 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claim 2 of copending U.S. Patent Application, Serial No.: 11/570,707 (the '707 application), in view of Gerster '340 and Kato. Applicant defers discussion of this provisional rejection until it matures into an actual rejection.

Please charge any unpaid fees associated with this Response, or credit any overpayments, to our Deposit Account No. 23/2825, under Docket No. C1271.70083US01 from which the undersigned is authorized to draw.

Dated: February 17, 2010

Respectfully submitted,

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